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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K 2690 - sch/msl	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DE99/01867	International filing date (*day/month/year*) 25 June 1999 (25.06.99)	Priority date (*day/month/year*) 26 June 1998 (26.06.98)
International Patent Classification (IPC) or national classification and IPC C12N 15/11		
Applicant DEUTSCHES KREBSFORSCHUNGSZENTRUM STIFTUNG DES ÖFFENTLICHEN RECHTS		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24 January 2000 (24.01.00)	27 September 2000 (27.09.2000)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/DE99/01867

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☒ the international application as originally filed.

☒ the description, pages 1-17, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-26, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig 1/21-21/21, as originally filed.
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20-22

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☒ the claims, or said claims Nos. 20-22 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

Claims 20-22 fail to satisfy the requirements of PCT Article 5:

It is not at all clear from the description that the claimed RNA molecules actually fulfill the function attributed to them. Also, the description does not contain any examples that would in any way verify the postulated effects of the claimed RNA. Therefore, **Claims 20-22**, which pertain to the use of RNA molecules for manufacturing drugs for the treatment of tumors or diseases of the central nervous system, are not supported by the description.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2,3,5,8-19,23-26	YES
	Claims	1,4,6,7	NO
Inventive step (IS)	Claims		YES
	Claims	2,3,5,8-19,23-26	NO
Industrial applicability (IA)	Claims	1-19, 23-26	YES
	Claims		NO

2. Citations and explanations

1) **Documents**

D1: Seager et al. (1979) Introductory Chemistry; p. 499; Figure 25.14

D2: Reichwald et al. (1998) EMBL sequence database Acc. No. AF031078

D3: Reichwald et al. (1998) EMBL sequence database Acc. No. AF030876

2) **Novelty and inventive step**

2.1) **Claim 1** pertains to an RNA molecule that can bind to a ligand and contains the following sequence areas: (a) a sequence area that maintains the three-dimensional structure of the RNA molecule and (b) a sequence area for the specific ligand binding.

A type of RNA that contains these features is, for example, transfer RNA (cf. D1). Therefore **Claim 1** and dependent **Claims 4 and 6** cannot be regarded as novel.

2.2) In light of the sequence indicated in D2 and D3, **Claim 7**, which pertains to a DNA sequence that codes

for the RNA molecule according to one of the preceding claims, cannot be regarded as novel.

2.3) **Claims 2, 3, 5, 8-19 and 23-26** formally satisfy the requirements of PCT Article 33(2):

D2 and D3 make it clear that the DNA sequence of Figure 1 is published in the EMBL Database. Since it is not clear, however, that said documents analyze or characterize the sequence in greater detail, they are not formally prejudicial to the novelty of **Claims 2, 3, 5 or 8-26.**

2.4) However, for the following reasons, **Claims 2, 3, 5, 8-19 and 23-26** cannot be recognized as involving an inventive step:

The computer-assisted analysis of already published DNA sequences and the potential characteristics and applications derived therefrom cannot be regarded as inventive without having been verified by means of at least one specific example. This applies in particular to the present claims which pertain to an undefined number of RNA molecules whose sole feature is that they contain both an area that can form a three-dimensional structure and an area that can bind to a ligand.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-7 do not satisfy the requirements of PCT Article 6.

Claim 1 is not characterized by technical features. Therefore the claimed RNA molecule is not sufficiently well defined, such that it seems to go beyond the scope of the task of the person skilled in the art to determine whether or not a given RNA molecule falls under the range of protection of the claim.

Claims 2 and 3 attempt to define the RNA molecule from Claim 1 more precisely. The wording selected therefor leads to a further lack of clarity. For example, it is not clear which area of Figure 3 is actually defined in Claim 2 or 3.

"The bar" on the edge of the claimed sequence signifies, for example, a sequence that can contain the nucleotides of 820-1020, 820-1021, 820-1023, etc., or 821-1020, 821-1021, etc. Claims 2 and 3 pertain further to "related sequences". According to the description (page 4), these can be any sequences that are not defined more specifically. Therefore the range of protection of the claims is not clear.

Furthermore, **Claims 2 and 3** fail to satisfy the requirements of PCT Article 6.2(a), which states that claims should not refer to figures.